UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION

No. 04-MDL-01592

This Document Relates To: All Cases

SUPPLEMENTAL MEMORANDUM OF PLAINTIFFS BIOGEN IDEC MA INC., GENZYME CORPORATION, ABBOTT BIORESEARCH CENTER, INC. AND GENENTECH INC. ADDRESSING PROSECUTION LACHES AND SUBJECT MATTER JURISDICTION PURSUANT TO THE COURT'S OCTOBER 7, 2004 ORDER

I. INTRODUCTION

The controversy between the parties concerning Columbia's unreasonable and unexplained delays in the prosecution of the '275 patent and '159 application is not obviated by Columbia's recently expanded covenant not to sue. The reasoning and holdings of both *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991) and *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479 (Fed Cir. 1996) indicate that they do not require dismissal of the case now before the Court, and at least one subsequent case confirms that the holdings of *Spectronics* and *GAF* apply only to claim-specific disputes such as infringement and validity.

II. SPECTRONICS AND GAF DO NOT ADDRESS ISSUES SUCH AS PROSECUTION LACHES THAT DO NOT TURN ON CLAIM SCOPE.

Columbia's arguments for dismissal of plaintiffs' prosecution laches claim are based on overbroad readings of *Spectronics* and *GAF*. In *Spectronics*, a case in which only infringement and validity were at issue, the patentee filed a covenant not to sue on its original patent after filing a reissue application with the PTO. The Federal Circuit affirmed the dismissal of the case for lack of subject matter jurisdiction notwithstanding the pending reissue application. In determining that the reissue application did not preserve subject matter jurisdiction, the Federal Circuit relied heavily on the fact that the scope of the reissue claims was not yet known. For example, the court reasoned that "no reissue patent claims yet exist by which infringement *vel non* can be measured." 940 F.2d at 634. The court continued:

The *claims* of the patent are the subject matter of the suit; they are sought to be declared invalid or non-infringed. The allegedly infringing product is to be measured against the *claims* set forth in the patent. ... Before a patent issues, and

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¹ Indeed, plaintiffs Biogen Idec MA Inc., Genzyme Corporation, Abbott Bioresearch Center, Inc., and Genentech Inc. join in Amgen's argument that Columbia's covenant does not go as far as *Spectronics* requires.

during the pendency of a patent application in the PTO, the courts have no *claims* by which to gauge an alleged infringer's conduct.

Id. at 636 (emphasis supplied). This reasoning does not remove the controversy now before this Court. The dispute remaining in the wake of Columbia's newly revised covenant stems not only from specific claims, but from the continuing threat of Columbia's two pending patent applications, the reissue of the '275 patent and the '159 application.

In *GAF*, the plaintiff had brought suit for a declaratory judgment of non-infringement and invalidity after receiving a cease-and-desist letter. The patent that was the subject of the threats had not yet issued at the time the plaintiff brought suit. The Federal Circuit affirmed the dismissal of the action for lack of subject matter jurisdiction. The court ruled that even though there was reasonable apprehension of suit and infringing activity, there could be no subject matter jurisdiction until the patent issued. Because the district court did not "know with certainty whether a patent would issue or, if so, what legal rights it would confer upon Elk" – *i.e.*, what the scope of the claims would be – the dispute was "purely hypothetical and called for an impermissible advisory opinion." 90 F.3d at 482. In explaining its ruling, the court reasoned that "Patent rights are created only upon the formal issuance of the patent; thus, disputes concerning patent validity and infringement are necessarily hypothetical before patent issuance." *Id.* at 483. In particular, the district court could not have provided "specific relief through a decree of a conclusive character," ... since there was no issued patent for the court to declare 'invalid' or 'not infringed." *Id.* at 482.

Here, by contrast, plaintiffs' prosecution laches claims center on Columbia's ongoing efforts to extract further licensing revenue based on research conducted in the late 1970's. The continued prosecution itself, and the threat to the biotechnology industry that this prosecution presents, do not turn only on the specific elements of the claims. If the threat posed by

Columbia's continued prosecution of its applications were not real and substantial, Johnson & Johnson and Wyeth would have had no motivation to settle after they were relieved of liability under the original '275 patent by virtue of Columbia's covenant. These announced settlements are a testimonial to the potency of the threat posed by further prosecution of Columbia's two pending applications.

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At least one court has recognized that the holdings of cases such as *Spectronics* and *GAF* should be limited to their facts. In Kowsower v. Gutowitz, No. 00 Civ. 9011 (JGK), 2001 WL 1488440 (S.D.N.Y. Nov. 21, 2001), the district court exercised subject matter jurisdiction over a case concerning inventorship of a *pending* patent application. The court distinguished GAF:

GAF [citation omitted] held only that a court cannot adjudicate a validity and infringement suit over a future patent because the dispute was purely hypothetical. In this case, the plaintiff seeks to correct a pending application and does not seek an adjudication of the validity or infringement of the yet-to-be issued patent.

2001 WL 1488440, *6, n.6.2 Thus, the court recognized that a pending patent application, such as the '159 application or the '275 reissue application, can still present an Article III case or controversy, even though there is always the possibility when an application is pending that no patent will issue at all. Cf. Heineken Tech. Servs., B.V. v. Darby, 103 F. Supp. 2d 476, 478–79 (D. Mass. 2000) (exercising subject matter jurisdiction over a dispute concerning inventorship of a pending patent application; parties did not raise question whether controversy was justiciable). In cases such as Kowsower, and in this case, a live controversy may exist even before the issuance of a patent.

² Some courts have dismissed inventorship claims relating to pending patent applications on the ground that the authority to correct inventorship of a pending application rests with the PTO. See, e.g., Murray v. Gemplus Int'l, S.A., No. Civ. A. 02-6265, 2002 WL 32107942, at *3 (E.D. Pa. Oct. 29, 2002). Compare 35 U.S.C. § 116 (authorizing PTO Director to correct inventorship on pending application) with 35 U.S.C. 256 (authorizing district court to correct inventorship on issued patent). These cases do not hold that there is no justiciable controversy in cases involving inventorship of a pending application.

Here, the controversy over prosecution laches is justiciable because Columbia's conduct in continuing to prosecute its applications greatly burdens the biotechnology industry's current and planned research and development efforts. This burden, and the consequent dispute, exist regardless of whether any claims ultimately issue from the '159 application or the '275 reissue application. This circumstance presents an additional reason why *Spectronics* does not require dismissal in this case. In *Spectronics*, the accused infringer did not present evidence, as plaintiffs here have, that its current product development was threatened by the pendency of the reissue application. Nor was there evidence that the patentee was using the threat of pending patent applications as leverage to extract settlements from the industry.

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At the hearing, Columbia cited cases dismissed for lack of subject matter jurisdiction where an accused infringer had raised an unenforceability defense. However, in those cases, there was no pending application, so the unenforceability defense raised no justiciable issues once the patentee covenanted not to sue under the original patent. Thus, it is irrelevant that *Spectronics*-type covenants may defeat subject matter jurisdiction where there is a claim of inequitable conduct (or, in theory, prosecution laches) but no further pending applications. *See*, *e.g.*, *Intellectual Prop. Dev.*, *Inc.* v. *TCI Cablevision of Cal.*, *Inc.*, 248 F.3d 1333, 1337 (Fed. Cir. 2001) (noninfringement, invalidity, and unenforceability due to inequitable conduct); *Fina Research S.A.* v. *Baroid Ltd.*, 141 F.3d 1479, 1480–81 (Fed. Cir. 1998) (same). Here, however, there are two pending patent applications that make this situation entirely different from the cases on which Columbia relies. If Columbia had no pending applications threatening the biotechnology industry – i.e., if the '275 patent had been Columbia's last chance to exact revenue from plaintiffs – plaintiffs would not be arguing that this Court has subject matter jurisdiction by virtue of their prosecution laches claims.

Moreover, the cases upon which Columbia relied involved inequitable conduct defenses, not prosecution laches. Prosecution laches occurs when a patentee, through dilatory conduct, unreasonably delays the time when the public may freely enjoy the invention. See Woodbridge v. United States, 263 U.S. 50, 56 (1923); Webster Elec. Co. v. Splitdorf Elec. Co., 264 U.S. 463, 465–66 (1924); Symbol Techs., Inc. v. Lemelson Med., 277 F.2d 1361, 1364–65 (Fed. Cir. 2002). A patent need not issue for this Court to make a determination that Columbia has forfeited its ability further to burden the public as a result of its dilatory conduct during prosecution. See In re Bogese, 303 F.3d 1362, 1364-65, 1369 (Fed. Cir. 2002) (upholding PTO rejection of pending claims for prosecution laches).

III. **CONCLUSION**

For the reasons set forth above and in plaintiffs' prior briefs in opposition to Columbia's emergency motion to dismiss for lack of subject matter jurisdiction, that motion should be denied. There is a real, not hypothetical, controversy concerning plaintiffs' continued prosecution of the reissue application and the '159 application.

Dated: October 12, 2004 Respectfully submitted,

/s/ Claire Laporte

Donald R. Ware (BBO # 516260) Claire Laporte (BBO # 554979) Sarah Cooleybeck (BBO # 631161) Carla Miriam Levy (BBO # 654212) FOLEY HOAG LLP 155 Seaport Boulevard

Boston, MA 02210-2600 Telephone: (617) 832-1000 Facsimile: (617) 832-7000

Attorneys for BIOGEN IDEC MA INC. and

GENZYME CORPORATION